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Remarks

Claims 1 to 54 remain pending in the application.

The Office Action rejects claims 1, 2, 19, 20, 37 and 38 as obvious over Montaldi, Sterilization Method and Apparatus, U.S. Patent 4,700,701 (Oct. 20, 1987) under the assertion that Montaldi discloses a method of occluding the ovarian pathway of a female body, the method comprising the steps of: applying a heating element to a target segment of the pathway, and operating the heating element to heat the target segment of the pathway; installing a plug into the target segment of the pathway and that Montaldi teaches all of the limitations of the claims except limiting the heating of the target segment by applying power of 0.1 to 5 watts to the heating element for a period of about 5 seconds. The Examiner further asserts that to have provided the power within the range claimed would have been obvious to one of ordinary skill in the art at the time the invention was made since it has been held that discovering the optimal workable range involves only routine skill.

Montaldi does not disclose applying a heating element to a target segment of the pathway. Instead, Montaldi discloses that the injury or destroyed portion of the mucosal lining be achieved by a cryogenic thermal exchange. In column 3, lines, 11-16, Montaldi states that "It is preferred that the peltier device produce a cold effect in the range of temperatures near -40° centigrade sufficient to severely injure or destroy by cauterization a portion of the mucosal lining in contac[t]e with the surface area of the peltier device." Injury caused to the mucosal lining by a heating element is not contemplated by

Montaldi. Further, in column 3, ll. 39-41, discloses that "a portion of the mucosal lining of the fallopian tube immediately adjacent the peltier device is thermally destroyed or cauterized by a **cryogenic thermal exchange.**" A cryogenic thermal exchange is not achieved using any type of heating element. Thus, Montaldi discloses no range of heating, so that the claimed range of heating cannot be obvious in view of Montaldi.

The cited references do not disclose all limitations of the claim. Even if it was assumed that the claimed heating step is achieved, the step of "limiting the heating of the target segment" is not achieved. The Examiner asserts that to have provided the power within the range claimed would have been obvious to one of ordinary skill in the art at the time the invention was made since it has been held that discovering the optimal workable range involves only routine skill. However, "[o]ne way for a patent applicant to rebut a prima facie case of obviousness is to make a showing of 'unexpected results,' *i.e.*, to show that the claimed invention exhibits some superior property or advantage that a person of ordinary skill in the relevant art would have found surprising or unexpected." *In re Soni*, 54 F.3d 746, 750, 34 USPQ2d 1684, 1687 (Fed. Cir.1995). If the "results of optimizing a variable" are "unexpectedly good" a patent can be obtained for the claimed critical range. *In re Antonie*, 559 F.2d 618, 620, 195 USPQ 6, 8 (CCPA 1977); *see also In re Dillon*, 919 F.2d 688, 692, 16 USPQ2d 1897, 1901 (Fed.Cir.1990) (in banc). The presumption applied by the Examiner can also be rebutted if it can be shown that the prior art teaches away from the claimed range, or the claimed range produces new and unexpected results. *Iron Grip*, 392 F.3d at 1322; *In re Geisler*, 116 F.3d at 1469;

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Applicant's rejected claims limit the heating of the target segment "by applying power of 0.1 to 5 watts to the heating element for a period of at least about 5 seconds." This is a specific range of power applied for a specific period of time. The Montaldi specification is void of any disclosed range other than identifying "cryogenic cooling" (a range of temperature near -40° centigrade). Therefore, Applicant's claimed range is not encompassed by the prior art (specifically below 5 watts). The examiner has merely assumed that the claimed range overlaps a range in the prior art, but has shown no reference to support the assumption and cannot cite any portion of the Montaldi patent that includes this range. Moreover, the cited reference teaches away from the claimed range because it teaches cryogenic cooling. Injury caused by cryogenic cooling is not the same as injury caused by application of a heating element of less than 5 watts. It is not considered a matter of routine experimentation to apply a heating element of less than 5 watts to cause injury where cryogenic cooling has been the disclosed method. The Examiner has not offered any proof that the claimed range could be considered a matter of routine experimentation particularly because it is not disclosed in the cited reference. Therefore, the claims are not obvious and the rejections should be withdrawn.

The Examiner has rejected claims 3-8, 21-26 and 39-44 as obvious over Montaldi in view of Schaer, Balloon Anchor Device, U.S. Patent 6,595,989 (Jul. 22, 2003) under the assertion that Schaer teaches that it is old and well known in the art to provide the heating element in the form of at least one electrode; two electrodes; bi-polar RF energy; one resistive heating element; at least one microwave; at least one ultrasound

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heating element; and at least one laser heating element. The Examiner further asserts that it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the various sources of energy with the Montaldi device in view of the teaching of Schaer. The references, when combined, do not result in the claimed invention. These claims depend from claims 1, 19 and 37 and as discussed above the rejection with respect to Montaldi is improper and thus these rejections should be withdrawn. As discussed above, Montaldi does not disclose application of a heating element with limited application of the heating element.

Schaer is non-analogous art. It is necessary to consider "the reality of the circumstances", in other words, common sense, in deciding in which fields a person of ordinary skill would reasonably be expected to look for a solution to the problem facing the inventor. In re Oetiker, 977 F.2d 1443, 1447 (Fed. Cir. 1992). Schaer is directed elimination of a region of tissue at the location where a pulmonary vein extends from an atrium in a patient. It would be utterly foolish to think that it would offer any insights into vessel occlusion, since vessel occlusion would kill the patient. While Montaldi and Schaer both relate to tissue ablation systems generally, Schaer is related to a system that relates to an entirely different part of the body. Different areas of the body require different treatment so it is not possible to create an over-arching art of "tissue ablation systems" generally where each system has different requirements. It would not be reasonably expected that a person interested in ablating tissue of the ovarian pathway would look to a pulmonary vein ablation device. Each system is complicated and requires its own considerations. Each

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system is highly sensitive and specific to the anatomy of each body system and therefore one would not be expected to look to the pulmonary vein to find correlation with the ovarian pathway. Therefore, Schaer is non-analogous art and accordingly the rejection related to these claims should be withdrawn.

The Examiner has rejected claims 9-18, 27-36 and 46-54 as obvious over Montaldi under the assertion that Montaldi teaches all of the limitations of the claims except providing the plug in the form of a reticulated foam plug having pores with pore size in the range of 40 to 200 microns; having pores with pore sizes in the range of 1 to 20 microns; a silicone having a durometer value of 20-100 Shore A; a silicone foam having a durometer value of about 60 Shore A; an ePTFE plug; an acrylic copolymer plug; a silicone foam having a durometer value of 20-100 Shore A; a silicone foam having a durometer value of about 6- Shore A; an ePTFE plug; and an acrylic copolymer plug. The Examiner further asserts that a plug constructed of the material as claimed would have been obvious to one of ordinary skill in the art at the time the invention was made since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. The Food and Drug Administration (FDA) has required applicant to conduct a Premarket Approval (PMA) study. Such information in the form of device description and intended use, nonclinical and clinical studies, case report forms, manufacturing methods, labeling, etc. would not be required where the FDA believed the use of a silicone plug would be merely a matter of design choice. Further, the cited reference teaches away from the suitability of the claimed materials. In column 4, ll. 10-18, Montaldi

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discloses that the final result is replacement of the muscle fibers in the exposed muscle tissue with a "support type of scar tissue that only bridges and does not function as the original tissue." Therefore, the "destroyed portion of the mucosal lining is replaced by scar tissue proceeding from the exposed muscle tissue and thereby results in the blockage." The materials used in applicant's claims are selected to allow the formation of vascularized tissue within the pores. Applicant's disclosure identifies that formation of scar tissue is not desirable because it leads to a "standard foreign body response" that will eventually operate to expel the plug (page 9, ll. 24 – page 10, ll. 17). One skilled in the art would not have selected the claimed materials for use with a Montaldi plug because the materials do not provide any advantage when used in a procedure that requires formation of scar tissue. It is not an obvious design choice to select the claimed materials because the function and desirable features of the Montaldi system are not reached using the claimed materials. Moreover, Montaldi discloses that the plug used be of "absorbable means." In column 4, ll. 10-14, it is disclosed that the final result is absorption of the entire absorbable means. Applicant's plug is formed of silicone, which is not absorbable, by the body. The silicone material is selected for its ability to support vascularized tissue and is not to be absorbed by the body. Montaldi does not teach plugs adapted to support vascularized tissue, thus these claims are not obvious in view of Montaldi.

Conclusion

This response has addressed all of the Examiner's grounds for rejection. The rejections based on prior art have been

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traversed. Reconsideration of the rejections and allowance of the claims is requested.

Date: February 8, 2007 By: _____

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